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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,548	07/30/2003	Ralph A. Backhaus	AP35352 072448.0362	7467

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EXAMINER

LANKFORD JR, LEON B

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/630,548	Applicant(s) BACKHAUS, RALPH A.	
	Examiner Leon Lankford	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Backhaus et al (6132711).

Backhaus disclose pharmaceutical compositions of allene oxide synthase in a pharmaceutical carrier. The reference clearly anticipates the claim 7 subject matter.

Claims 4-6 require a preventing effect by the administration of the enzyme. As Backhaus teaches an administration of the enzyme to an individual, the same prophylaxis effects claimed must have been accomplished in the earlier method of Backhaus. As the target (an individual) and the steps (administration of the enzyme) are identical in the instant claims and in the patent, any result of the instant claims must have been inherently accomplished by the patent's method. The reference anticipates the claim subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Backhaus et al (6132711).

Backhaus disclose pharmaceutical compositions of allene oxide synthase in a pharmaceutical carrier. It would have been obvious at the time the invention was made to treat ischemic injuries, myocardial or cerebrovascular, because the reference clearly suggests the use of the enzyme preparation to treat ischemic disorders as the enzyme works well as an enzymatic antioxidant acting particularly on lipid peroxides:

Antioxidants, such as beta-carotene, SOD, allopurinol, and catalase, have been used in treating ischemia following surgery or injury in biological organisms. (Konovalova et al., Arkh. Patol. 51(6): 19-24 (1989) (Abstract);

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Minor et al., Surg. Today 23(8): 728-732 (1993) (Abstract); Maksimenko et al., Eksp. Kin. Farmakol. 56(5): 14-18 (1993) (Abstract); Kloner, Circ. Res. 64:(1): 86-96 (1989) (Abstract); Nayak et al., Invest. Ophthalmol. Vis. Sci. 34(6): 2018-2022 (1993) (Abstract); Baker et al., Ann. Surg. 202(5): 628-641 (1985) (Abstract); Gross et al., Am. J. Physiol. 250(3Pt.2): H372-H377 (1986) (Abstract); Zweier et al., J. Clin. Invest. 80(6): 1728-1734 (1987) (Abstract); Singh et al., Mol. Cell. Biochem. 125(2): 97-104 (1993); Nelson et al., Free Radic. Biol. Med. 16(2): 195-200 (1994) (Abstract); Burton, Am. J. Physiol. 248(5 Pt. 2): H637-H643 (1985) (Abstract); Chi et al. Circ. Res. 64(4): 665-675 (1989) (Abstract); Miura et al. Jpn. Circ. J. 53(7): 786-794 (1989) (Abstract); Konovalova et al. Biull Eksp Biol. Med. 98(8): 153-156 (1984) (Abstract); Gutkin et al. Biull. Eks. Biol. Med. 93(1): 33-35 (1982) (Abstract); and Wang et al., Hua. Hsi. I. Ko. Ta. Hsueh. Pao. 25(1): 62-65 (1994) (Abstract)). Ischemia is a deficiency of blood in a biological organism due to functional constriction or actual obstruction of a blood vessel, common in surgery, that causes cell tissue damage as a result of oxidation. Myocardial ischemia is a deficiency of blood supply to the heart muscle.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 7 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6132711. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims render obvious the instant claims by actually anticipating them.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4-6 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a credible utility.

The prevention of ischemic injury is deemed to be an incredible utility because prevention is an absolute limitation. It is not credible to allege that the administration of pharmaceutical compositions of allene oxide synthase will prevent any and all

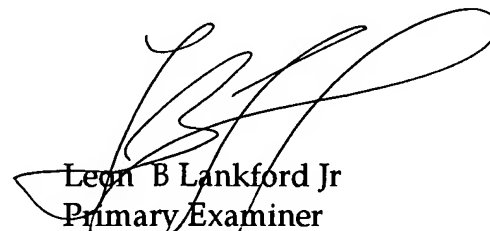
occurrences of ischemic injuries particularly myocardial or cerebrovascular. The specification does not demonstrate this to the level required by a claim to "prevention."

Claims 4-6 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a credible utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Lankford whose telephone number is 571-272-0917. The examiner can normally be reached on Mon-Thu 7:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leon B Lankford Jr
Primary Examiner
Art Unit 1651